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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,490	02/07/2002	J. Alexander Marchosky	60019660-0021	2740

26263 7590 01/23/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte J. ALEXANDER MARCHOSKY

Appeal 2008-6234
Application 10/071,490
Technology Center 1600

Decided: January 23, 2009

Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and JEFFREY N. FREDMAN, *Administrative Patent Judges.*

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal from the Examiner's final rejection of claims 97, 98, and 103-108. Jurisdiction is under 35 U.S.C. § 6(b). We affirm the rejection.

STATEMENT OF THE CASE

The claims are directed to a composition for promoting the growth and strengthening of bone "consisting essentially of" hyaluronic acid (or a

salt of it), cancellous bone, demineralized bone matrix, and non-decalcified bone matrix, where each component is present in a specific concentration.

Claims 97, 98, and 103-108 are pending and stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for lack of written description (Ans. 4). The only independent claim on appeal is claim 104. Because claims 97, 98, 103, and 105-108 depend on claim 104 and incorporate all its limitations, we select claim 104 as representative. Claim 104[1] reads as follows:

> 104. A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid or a salt thereof, cancellous bone, demineralized bone matrix, and non-decalcified bone matrix,
> wherein the hyaluronic acid or salt thereof is present as a 0.5%-5% (w/v) gel concentration at 10-80% (w/w); the cancellous bone is milled to 0.1-1.5 mm in its longest diameter and is present at 10-40% (w/w); the demineralized bone matrix is present at 5-30% (w/w); and the non-decalcified bone matrix is present at 5-30% (w/w).

ISSUE

Does the Specification provide a written description of a composition consisting essentially of hyaluronic acid (or a salt of it), cancellous bone, demineralized bone matrix, and non-decalcified bone matrix, where each component is present in a specific recited concentration?

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[1] In an amendment (Mar. 19, 2007) denied entry by the Examiner (Apr. 24, 2007), Appellant had attempted to cancel the "wherein" clause from claim 104. Appellant indicated this cancellation by bracketing the entire clause (Mar. 19, 2007 Amendment, page 2). In the claim appendix to their Brief (page 20), Appellant erroneously included the brackets around the "wherein" clause. This clause has not been deleted from the claim and we therefore list it here without the brackets.

PRINCIPLES OF LAW

> "Consisting essentially of" is a transition phrase commonly used to signal a partially open claim in a patent. Typically, "consisting essentially of" precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.

PPG Industries Inc. v. Guardian Industries Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

To satisfy the written description requirement, the inventor "must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). In describing the claimed invention, there is no requirement that the wording be identical to that used in the specification as long as there is sufficient disclosure to show one of skill in the art that the inventor "invented what is claimed." *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000).

An applicant complies with the written description requirement "by describing the invention, with all its claimed limitations." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

BACKGROUND

Claim 104, the only independent claim which is pending in this appeal, was added by amendment during prosecution of this application.[2] In response to the amendment, the Examiner sent a Notice of Allowance to

[2] Amendment (Mar. 6, 2006).

Appellant, stating that the claims had been allowed for issuance of a patent.[3] However, the Examiner later withdrew the allowance, and in a subsequent Office Action, rejected claim 104 under 35 U.S.C. § 112, first paragraph, for lack of written description.[4] The Examiner stated that claim 104 contained subject matter which was not described in the Specification as originally filed.

Independent claim 104 is drawn to a composition "for promoting the growth and strengthening of bone." The composition "consist[s] essentially" of a mixture of four components:

(1) hyaluronic acid or salt thereof ("HA");

(2) cancellous bone ("CB");

(3) demineralized bone matrix ("DBM"); and

(4) non-decalcified bone matrix ("NBM").

The claim also specifies the concentration of each component in the composition.

The composition of claim 104 "consisting essentially of" four specific components was not originally claimed. The Examiner's position is that the claimed composition "consisting essentially" of HA, CB, DBM, and NBM in the recited amounts "was not envisioned at filing" (Ans. 5). The Examiner explains: "There is nothing in the specification pointing to this specific combination of components and amounts" (*id.*).

[3] Notice of Allowance (May 24, 2006).
[4] Office Action (Aug. 25, 2006).

FINDINGS OF FACT (FF)

1. In the *Summary of the Invention*, a composition for promoting growth and strengthening of bone is described that comprises: 1) a mixture of HA, 2) CB, and, 3) DBM (Spec. 5:27 to Spec. 6:3). This composition was claimed in the original Specification (Spec. 43; claim 56).

2. A composition is described in the *Summary of the Invention* having an osteoinductive material (b) that comprises: 1) DBM, 2) NBM, and 3) "with or without" HA (Spec. 4:9-10; 5:7-9). This composition is also described on page 16, lines 6-9, of the Specification (*see* FF4 below).

3. In addition to DBM, NBM, and HA, the composition (FF2) can comprise CB (Spec. 4:12) and growth factors (*id.* at 4:1-9).

4. The Specification states

> Certain complex materials can also conveniently serve as sources of osteoinductive molecules. Such molecules are known to be provided by demineralized bone matrix ("DBM"), which is prepared by grinding cortical bone tissues . . . , then treating the ground tissues with hydrochloric acid . . . It is believed, however, that the acid treatment process used in preparing DBM denatures and/or solubilizes some of the osteogenic molecules present in untreated bone, destroying the osteogenic nature of the denatured molecules or allowing them to leach out of the DBM preparation. Therefore, a preferred source of osteogenic molecules is non-decalcified bone matrix ("NBM"), which is ground cortical bone tissues which are not acid-treated. A combination of [NBM] protein and DBM is also useful in the invention compositions as a source of osteoinductive molecules. The addition of [HA] may further enhance the osteoinductivity of the mixtures.

(Spec. 15:15 to 16:9.) Osteoinductive materials act as bone growth factors (*id.* at 9:14-22).

5. The compositions explicitly described in the Specification are summarized in the table below, where "+" indicates the presence of the component and a blank, its absence.

	HA	CB	DBM	NBM
FF1	+	+	+	
FF2	+		+	+

6. There is no word-for-word description of a composition consisting essentially of: 1) HA, 2) CB, 3) DBM, and 4) NBM as required by claim 104.

ANALYSIS

The issue in this case is whether the Specification contains a written description of the composition of claim 104 "for promoting the growth and strengthening of bone" which consists essentially of HA, CB, DBM, and NBM. A composition consisting essentially of all four recited components is not explicitly disclosed in the Specification (*see* FF1-6). Instead, the Specification describes a three-component composition of HA, CB, and DBM (FF1). Citing the Specification at page 16, lines 5-8, Appellant contends that "the use of the combination of NBM and DBM, as an alternative [for] DBM alone" is "*expressly provided for*" (App. Br. 18). Appellant's position is apparently that persons of ordinary skill in the art would have recognized the description of the claimed four-component composition when DBM and NBM is substituted for DBM in the three-component composition summarized in FF1 (*id.*).

According to the Specification, DBM is a source of osteoinductive molecules that serve as bone growth factors (FF4). The Specification states that there is a loss in the osteoinductive molecules when DBM is prepared (FF4). Consequently, the Specification states that "a preferred source" of the osteoinductive factors is NBM, rather than DBM (FF4; Spec. 16:3-5). For this reason, the Specification concludes – as Appellant noted – "[a] combination of [NBM] protein and DBM is also useful in the invention compositions as a source of osteoinductive molecules" (FF4; Spec. 16:5-8).

This disclosure is not sufficient to establish that the inventor invented the claimed four-component composition. To satisfy the written description requirement, the Specification must convey to persons of ordinary skill in the art that the inventor was in possession of the claimed invention. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563-64. In this case, the Specification describes a three-component composition of HA, CB, and DBM in the *Summary of the Invention* and claims it (FF1). However, there is no explicit statement in the written description that the inventor invented this same composition with NBM. Appellant provides a reason as to why NBM might be added to the three-component composition: because the Specification is said to teach that the combination of NBM and DBM is an alternative for DBM, alone (FF4; App. Br. 18). However, this was stated in the context of describing an osteoinductive material (FF3). There is no statement in the Specification that this substitution should be made in a different composition having only HA, CB, and DBM (FF1).

Appellant appears to be relying an improper standard for complying with the written description requirement for a claim which was not disclosed in the original application - as is the here. The question is not whether the

Specification provides a *reason* to have made the invention which is now claimed, but whether the invention, with all its claimed limitations, is described in it. *See Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (1997). In the *Summary of the Invention*, a composition for promoting growth and strengthening of bone is described that contains: 1) HA, 2) CB, and, 3) DBM (FF1). The inventor therefore expressly summarized what he believed the invention to be: a composition of HA, CB, and DBM. This express statement of the invention should be taken at face value. To find otherwise, would improperly extend the scope of the invention beyond what was actually described as in the Specification.

CONCLUSION OF LAW

The Specification does not describe a composition consisting essentially of hyaluronic acid (or a salt of it), cancellous bone, demineralized bone matrix, and non-decalcified bone matrix, where each component is a specific concentration. We affirm the rejection of claim 104, and dependent claims 97, 98, 103, and 105-108 which incorporate all its limitations and which were not separately argued. *See* 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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